K070307

SECTION 5: 510(k) SUMMARY

MAY - 2 2007

DENTSPLY Internatior
Susquehanna Commerce Center We
221 West Philadelphia Street, Suite (
York, PA 17405-08

CONTACT: Helen Lewis

DATE PREPARED: January 31, 2007

TRADE OR PROPRIETARY NAME: Steri-Mate Handpiece Sleeve with LED Light

CLASSIFICATION NAME: Scaler, Ultrasonic
CLASSIFICATION: Class II
REGULATION NUMBER: 21CFR 872.4850

PREDICATE DEVICES: Steri-Mate Handpiece for Cavitron JET Unit (CJ Handpiece), K941392

DEVICE DESCRIPTION:
The Steri-Mate Handpiece Sleeve with LED Light is an accessory that easily slides over the Steri-Mate handpiece (predicate device) to generate a focused light to illuminate the clinician's working area during an ultrasonic procedure. The sleeve uses the energy generated from the Steri-Mate handpiece to generate light output when the ultrasonic unit's foot control is activated.

INTENDED USE:
1. Provides illumination to enhance visibility in the clinical working area during ultrasonic scaling procedures with the Steri-Mate handpiece. 2. When the lighted sleeve is installed on the Steri-Mate handpiece, the soft tapered grip provides multiple pinch points, to enhance ergonomics and improve clinician comfort. 3. The Steri-Mate handpiece with the lighted sleeve is steam sterilizeable which reduces the risk of cross contamination.

TECHNOLOGICAL CHARACTERISTICS:
All of the components found in Steri-Mate Handpiece Sleeve with LED Light have been used in legally marketed devices and/or were found safe for dental use. The Steri-Mate Handpiece Sleeve with LED Light has been evaluated and passed biocompatibility testing for L929 MEM Elution Test - ISO, Oral Irritation Test - Acute Exposure - ISO and Kligman Maximization Test - ISO.

We believe that the prior use of the components of the Steri-Mate Handpiece Sleeve with LED Light in legally marketed devices, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of the Steri-Mate Handpiece Sleeve with LED Light for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2007

Ms. Helen Lewis
Director of Corporate Compliance & Regulatory Affairs
DENTSPLY International, Incorporated
221 West Philadelphia Street, Suite 60
Susquehanna Commerce Center
York, Pennsylvania 17404

Re: K070307
Trade/Device Name: Steri-Mate Handpiece Sleeve with LED Light
Regulation Number: 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: January 31, 2007
Received: February 1, 2007

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

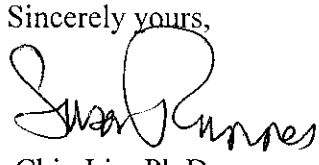
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K070307

Device Name: Steri-Mate Handpiece Sleeve with LED Light

Indications for Use:

The Steri-Mate Handpiece Sleeve with LED Light is indicated for:
1. Provides illumination to enhance visibility in the clinical working area during ultrasonic scaling procedures with the Steri-Mate handpiece.
2. When the lighted sleeve is installed on the Steri-Mate handpiece, the soft tapered grip provides multiple pinch points, to enhance ergonomics and improve clinician comfort.
3. The Steri-Mate handpiece with the lighted sleeve is steam sterilizeable which reduces the risk of cross contamination.

Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K070307

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)